

NATURAL RESOURCES AND ENVIRONMENTAL PROTECTION ACT (EXCERPT)
Act 451 of 1994

PART 205
LABORATORY DATA QUALITY ASSURANCE

324.20501 Citation of part.

Sec. 20501. This part may be cited as the “V. Harry Adrounie laboratory data quality assurance act”.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20503 Definitions.

Sec. 20503. As used in this part:

(a) “Analytical data” means the qualitative or quantitative measurements generated by chemical, physical, biological, microbiological, radiological, or other scientific determination.

(b) “Calibration” means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards established as follows:

(i) In calibration of support equipment, through the use of reference standards that are traceable to the international system of units.

(ii) In calibration according to analytical methods, typically through the use of reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

(c) “Commercial laboratory” means a privately owned laboratory that generates analytical data required under this act pertaining to the operations of a third person regulated under this act.

(d) “Council” means the laboratory data quality assurance advisory council created in section 20517.

(e) “Department” means the department of environmental quality.

(f) “Director” means the director of the department.

(g) “Fund” means the laboratory data quality recognition program fund created in section 20509.

(h) “In-house laboratory” means a privately owned laboratory that generates analytical data required under this act pertaining to the operations of the owner of that laboratory or an affiliate of the owner.

(i) “Laboratory” means a body that engages in calibration or testing, or both, at a specified location.

(j) “Proficiency testing” means a method of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

(k) “Public laboratory” means a municipal or other publicly owned laboratory that generates analytical data for submission to the department under this act.

(l) “Quality recognition program” means the laboratory data quality recognition program provided for in section 20505.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20505 Laboratory data quality recognition program; purpose; implementation; participation by commercial laboratory.

Sec. 20505. (1) The department shall implement a laboratory data quality recognition program to identify commercial laboratories that the department considers to be qualified to generate analytical data for submission to the department for compliance purposes under this act.

(2) Participation in the quality recognition program by a commercial laboratory is voluntary. A commercial laboratory shall not be restricted or prohibited from generating analytical data for submission to the department for compliance purposes under this act based on nonparticipation or unsuccessful participation in the quality recognition program.

(3) Each time the department lets a contract or contracts for state-funded laboratory work authorized under this act, the department shall use only those commercial laboratories that are successful participants in the quality recognition program. Exceptions may be made if desired analytical support services are not available from a commercial laboratory that is a successful participant in the quality recognition program.

(4) The quality recognition program shall determine whether the quality of analytical data is maintained through quality systems in which staff responsibilities and operational procedures are defined, documented, and subjected to an internal assessment by the commercial laboratory itself on a regular basis, with timely corrective action taken by the commercial laboratory as needed. The quality systems shall include quality assurance policies and quality control procedures and shall be documented in a written plan.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20507 Participation in quality recognition program; duties of commercial laboratory.

Sec. 20507. To participate in the quality recognition program, a commercial laboratory shall do all of the following:

- (a) Submit an application to the department.
- (b) Pay the department a fee based on the department's actual costs of administering the quality recognition program but not exceeding \$750.00 for an initial application or \$500.00 for a renewal application.
- (c) Grant the department access to the laboratory and laboratory records for inspections during normal business hours without prior notice.
- (d) If required by the department, participate in proficiency testing conducted by the department, the United States environmental protection agency, or any other nationally recognized proficiency testing program.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20509 Laboratory data quality recognition program fund; creation; disposition of fees; investment; lapse; expenditures.

Sec. 20509. (1) The laboratory data quality recognition program fund is created within the state treasury.

(2) Fees collected under section 20507 shall be deposited in the fund. The state treasurer may also receive money or other assets from any other source for deposit into the fund. The state treasurer shall direct the investment of the fund. The state treasurer shall credit to the fund interest and earnings from fund investments.

(3) Money in the fund at the close of the fiscal year shall remain in the fund and shall not lapse to the general fund.

(4) The department shall expend money from the fund, upon appropriation, only to administer the quality recognition program.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20511 Website; information to be posted; recognition or termination of participation.

Sec. 20511. (1) Subject to subsection (3), the department shall maintain and post on its website all of the following information:

(a) A list of laboratories that have successfully participated in the quality recognition program together with a statement that substantially sets forth the provisions of section 20505(2) and (3).

(b) The types of analytical data with respect to which a laboratory successfully participated in the quality recognition program, if the laboratory successfully participated only with respect to certain types of analytical data.

(2) Subject to subsection (3), the successful participation of a commercial laboratory in the quality recognition program shall be recognized by the department as provided in subsection (1) and section 20505(3) for a 2-year period. A laboratory may apply under section 20507 to renew its participation in the quality recognition program.

(3) The department may terminate recognition of a commercial laboratory as a successful participant in the quality recognition program upon determining that the commercial laboratory no longer meets the standards for successful participation in the quality recognition program.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20513 Performance post audits; conduct and report by auditor general.

Sec. 20513. (1) The auditor general shall conduct performance post audits covering all of the following:

- (a) The quality of the analytical data generated by the department's environmental laboratory.
 - (b) The costs of operating the department's environmental laboratory relative to the costs of operating comparable private laboratories that meet the requirements for successful participation in the quality recognition program, to the extent sufficient data is available.
 - (c) The adequacy of the fees provided for in section 20507.
- (2) The auditor general shall conduct and submit to the legislature a report on a performance post audit described in subsection (1) within 1 year after the effective date of this section and every 2 years thereafter.

History: Add. 2004, Act 230, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20515 Rules.

Sec. 20515. The department shall enforce this part and, pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, may promulgate rules as it considers necessary to carry out its duties under this part. However, the department shall not promulgate any additional rules under this part after December 31, 2006.

History: Add. 2004, Act 229, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20517 Laboratory data quality assurance advisory council; creation; membership; appointment; term of service; vacancy; meetings; quorum; compensation; reimbursement.

Sec. 20517. (1) The laboratory data quality assurance advisory council is created in an advisory capacity within the department.

(2) The council shall consist of all of the following individuals:

- (a) A representative of a statewide business organization.
- (b) A representative of commercial laboratories that do not also function as in-house laboratories.
- (c) A representative of in-house laboratories.
- (d) A representative of public laboratories.
- (e) A representative of the Michigan municipal league or a successor organization.
- (f) A representative of the general public.
- (g) The director or his or her designee.

(3) The members of the council described in subsection (2)(a) to (f) shall be appointed by the governor. The members first appointed to the council shall be appointed within 90 days after the effective date of this section.

(4) Members of the council shall serve until a successor is appointed.

(5) If a vacancy occurs on the council, the unexpired term shall be filled in the same manner as the original appointment was made.

(6) The first meeting of the council shall be called by the director or his or her designee on the council. At the first meeting, the council shall elect from among its members a chairperson and other officers as it considers necessary or appropriate. After the first meeting, the council shall meet at least quarterly, or more frequently at the call of the chairperson or if requested by 2 or more members.

(7) A majority of the members of the council constitute a quorum for the transaction of business at a meeting of the council. A majority of the members present and serving are required for official action of the council.

(8) The director or his or her designee shall serve on the council without any additional compensation. Other members of the council shall serve without compensation. However, members of the council may be reimbursed for their actual and necessary expenses incurred in the performance of their official duties as members of the council.

History: Add. 2004, Act 228, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA

324.20519 Council; duties; disbandment.

Sec. 20519. (1) The council shall do all of the following:

(a) Monitor and evaluate the quality recognition program, including, but not limited to, both of the following:

(i) Whether commercial laboratories participating in the quality recognition program should or should not be required to participate in proficiency testing.

(ii) The structure and the appropriate scope of review of quality systems described in section 20505(4).

(b) Develop recommendations whether the program under this part should be retained, terminated, or replaced with another laboratory data quality assurance method.

(c) Evaluate the costs to private business of the program under this part and the costs to private business of implementing the recommendations under subdivision (b).

(d) Evaluate the first report of the auditor general under section 20513.

(e) Develop recommendations whether a commercial laboratory code of ethics is needed and, if so, what its content should be.

(f) Review the department's laboratory data acceptance requirements.

(g) Develop recommendations whether the department should provide additional technical and training assistance to commercial laboratories, in-house laboratories, and public laboratories.

(h) Submit to the governor, the senate majority leader, the speaker of the house of representatives, and the standing committees of the senate and house of representatives with primary responsibility for environmental protection issues reports on its findings under subdivisions (a) to (g). The council shall submit an interim report within 18 months after the effective date of this section and a final report by June 30, 2007.

(2) Effective 180 days after the council submits its final report as required by subsection (1)(h), the council is disbanded.

History: Add. 2004, Act 228, Imd. Eff. July 21, 2004.

Popular name: Act 451

Popular name: NREPA